PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX

Plastic box with 5 x 1 dose vial of vaccine and 5 x 1 ml vial of solvent
Plastic box with 25 x 1 dose vial of vaccine and 25 x 1 ml vial of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DP lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (1 ml) contains:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$

3. PACKAGE SIZE

5 x 1 dose of vaccine including 1 ml solvent
25 x 1 dose of vaccine including 1 ml solvent

4. TARGET SPECIES

Dogs (puppies)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 minutes.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not transport above 30 °C.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

Distributor:
Virbac Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 01708/5076

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE VIAL LABEL (LYOPHILISATE – 1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DP

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

Live attenuated canine distemper virus ~~$10^{5.1}$ – $10^{6.5}$ $TCID_{50}$/ml~~
Live recombinant canine parvovirus ~~$10^{5.1}$ – $10^{6.7}$ $TCID_{50}$/ml~~

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 30 minutes.

5. ROUTE(S) OF ADMINISTRATION

SC

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Virbac logo (Distributor: Virbac Ltd.)

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT LABEL

SOLVENT VIAL LABEL (1 ml)

1. NAME OF THE DILUENT/SOLVENT

Solvent for Canigen DP

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

3. ROUTES OF ADMINISTRATION

SC

4. STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac logo (Distributor: Virbac Ltd.)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DP lyophilisate and solvent for suspension for injection for dogs (puppies)

2. COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Live attenuated canine distemper virus strain Onderstepoort: $10^{5.1}$ – $10^{6.5}$ $TCID_{50}$*
Live recombinant canine parvovirus strain 630a: $10^{5.1}$ – $10^{6.7}$ $TCID_{50}$*

*Tissue culture infective dose 50%

Lyophilisate: off-white or cream-colour.
Solvent: clear colourless solution.

3. TARGET SPECIES

Dogs (puppies).

4. INDICATIONS FOR USE

For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

Onset of immunity: for canine distemper virus: 7 days.
for canine parvovirus: 3 days.
Duration of immunity: 8 weeks.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Moderate to high levels of maternally derived antibodies against canine distemper virus can reduce the efficacy of the product against canine distemper.
It is typically advised that each pup is vaccinated with this product at 6 weeks of age. In cases where there is a high risk of canine parvovirus infection and/or canine distemper virus infection, it is advised that pups are vaccinated earlier, but not before 4 weeks of age. The routine vaccinations with core vaccines against canine distemper, canine parvovirosis, canine contagious hepatitis and respiratory disease caused by adenovirus type 2 infection should be given as indicated in the package leaflets of these products.

In some puppies the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease. In cats the virus may be shed up to 5 days and spread to other cats without causing any signs of disease. Canine distemper virus is not spread by vaccinated puppies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccine in the Canigen range containing *Bordetella bronchiseptica* and parainfluenza virus components for intranasal administration. Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:
No adverse reactions other than those mentioned in section “Adverse Events” were observed after administration of a 10-fold overdose of the vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

7. ADVERSE EVENTS

Dogs:

Very common (>1 animal / 10 animals treated):	Injection site swelling.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Lethargy.[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.[3]

[1] Small, non-painful swelling (≤ 1 cm diameter) within the first week after vaccination. The swelling will resolve completely within a few days.
[2] Within 4 hours after vaccination.
[3] Including anaphylaxis (sometimes fatal). If such a reaction occurs, appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

Administer one dose (1 ml) to puppies from 4 weeks of age onwards.

Reconstitute the vial containing the lyophilisate with the supplied solvent.
Administer the total contents of the vial.

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that the lyophilisate is completely reconstituted before use.
Reconstituted product: off-pink or pink coloured suspension.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not transport above 30 °C.
Do not freeze. Protect from light.

Solvent: This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label . The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 30 minutes.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 01708/5076

Pack sizes:
- Plastic box with 5 x 1 dose vial of vaccine and 5 vials containing 1 ml of solvent.
- Plastic box with 25 x 1 dose vial of vaccine and 25 vials containing 1 ml of solvent.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Distributor and contact details to report suspected adverse reactions:
Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Suffolk
IP30 9UP
Tel.: +44 (0)1359 243243

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

The vaccine stimulates active immunity in puppies against canine parvovirus and canine distemper virus infection. Maternally derived antibodies against canine parvovirus do not interfere with the efficacy of this product. Immunity against canine distemper virus is achieved in animals of 4 weeks of age with low to moderate levels of maternal antibodies.

Approved 23 January 2024